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In re Application of :
SCHENK :
Serial No. : 09/724,575 :
Filed : 28 NOVEBMER 2000 :
Attorney Docket No.: 015270-00591US :

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.181 filed on 30 December 2003. The delay in acting upon this petition is regretted.

BACKGROUND

On 27 March 2002, the Office set forth a seven-way Restriction Requirement of the original 57 claims. The action also set forth an additional Restriction Requirement within Groups I-VI as follows:

> The claims of Groups I-VI are drawn to a multitude of amyloid components, agents, fibril components, as recited in claims 3, 5-6, 13, 15, 34-35 and 49-50. This constitutes a recitation of an implied mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the amyloid components, agents and fibril components are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.
>
> Upon election of one of Groups l-VI, Applicant is additionally required to elect a single amyloid component, i.e Applicant must elect one amyloid component, agent and fibril components from each of claims 3, 5-6, 13, 15, 34-35 and 49-50, (depending on the inventive Group, which is elected). This requirement is not to be considered as a requirement of an election of species, since each of the compounds recited in alternative from is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

It is this additional restriction requirement which is of issue in the petition.

Applicants responded on 9/26/02 with the election with traverse of Group II, Claims 11-25, drawn to a method of preventing or treating a disorder characterized by amyloid deposition by administering an agent effective to induce an immune response against an amyloid component. Applicants also elected with traverse transthyretin of claim 13 and ATTR fragment of claim 15. Applicants stated that the election of the transthyretin is based upon the assumption that the examiner intended to require an election of a precursor protein, not an amyloid component from claim 13.

The Office mailed an Office action on 11/21/02, in which the Examiner considered the election and traversal, as follows.

> Applicant's election with traverse of Group II (claims 11-25) as claim l 3 reads on transthyretin and claim 15 reads on ATTR in Paper No.9 (26 September 2002) is acknowledged. The traversal is on the grounds that there is nothing in the Examiner's Election/Restriction requirement (Paper No. 7) to excuse a refusal to examine an elected invention or a generic claim reading thereon. This is not found persuasive because the precursor proteins listed in claim 13 and their respective fragments listed in claim 15 are not members of a Markush group. Each protein/fragment pair belongs to independent and distinct diseases and disorders. Each would require an independent, non-overlapping, and distinct search; therefore the restriction requirement is maintained. Claims 1-10 and 26-57 from further consideration pursuant to 37 CFR 1.l42(b), as being drawn to a nonelected material, there being no allowable generic or linking claim. Claims 11-25 will be examined to the extent that they read on a method of preventing or treating a disorder characterized by amyloid deposition in a mammalian subject, comprising administering to a subject a dosage of transthyretin or ATTR effective to produce an immune response against an amyloid component characteristic of said disorder.

The restriction requirement was not made final in the Office action mailed 11/21/02. Claims 11-25 were examined, in part, to the extent that they read upon the elected invention and rejected under 35 USC 112, first paragraph for lack of enablement, under 35 USC 101 for double patenting and under judicially created doctrine of obviousness-type double patenting with various other applications.

Additionally, on page 5 of the Office action, Claims 11-25 were objected to "because of the following informalities: specifically recite non-elected material. Appropriate correction is required."

A final Office action was mailed on 7/25/03, in which the examiner maintained the restriction requirement and the objection to claims 13, 15 and 16, as follows:

> The objection to claims 13, 15, and 16 as set forth at pp. 5P8 of the previous Office Action (Paper No. 9, 21 November 2002) is maintained. Until a decision is reached concerning the Applicant's petition, claims 13, 15, and 16 contain

unelected material. The restriction requirement is still in effect and therefore the objection is maintained.

It appears from the previous passage that the objection to claims 11-12, 14, 17-19, 21-25 has been withdrawn though it is not clear from the record why this was done. Claims 11-12, 14, 17-19, 21-25 also encompass additional inventions. The rejection of Claims 11-19 and 21-25 was maintained under 35 USC 112, first paragraph for lack of enablement, under 35 USC 101 for double patenting and under judicially created doctrine of obviousness-type double patenting with various other applications.

The restriction requirement was made final when the Office action mailed 7/25/03 was made final.

Applicants filed a Notice of Appeal on 12/29/03 concurrently with the petition to review the finality of restriction requirement and an amendment. Claims 1-10, 20, and 26-57 were cancelled. Claims 58-73 were added. Claim 11 was amended. Claims 11-19, 21-25, and 58-73 are under examination.

Relevant claims as amended on 12/29/03 are reproduced below.

Claim 11. A method of treating a disorder characterized by amyloid deposition in a mammalian subject, comprising administering to the subject a dosage of an agent effective to produce an immune response comprising antibodies against an amyloid component characteristic of said disorder and an adjuvant that augments the immune response to the amyloid component, and thereby treating the disorder.

Claim 12. The method of claim 11, wherein said amyloid component is a fibril protein or fibril peptide.

Claim 13. The method of claim 11, wherein the amyloid component is derived from a precursor protein selected from the group consisting of Serum Amyloid A protein (ApoSSA), immunoglobulin light chain, immunoglobulin heavy chain, ApoAI, transthyretin, lysozyme, fibrogen alpha chain, gelsolin, cystatin C, Amyloid Beta protein precursor (Beta-APP), Beta2 microglobulin, prion precursor protein (PrP), atrial natriuretic factor, keratin, islet amyloid polypeptide, a peptide hormone, and synuclein; including variant proteins associated with hereditary amyloidosis.

Claim 14. The method of claim 13, wherein said agent induces an immune response directed against a neoepitope formed by said amyloid component with respect to said precursor protein.

Claim 15. The method of claim 13, wherein said amyloid component is selected from the group consisting of AA, AL, ATTR, AapoAl, Alys, Agel, Acys, Abeta, AB2M, AScr, Acal, AIAPP and synuclein-NAC fragment.

Claim 58. A method of prophylaxis of a disorder characterized by amyloid deposition in a mammalian subject, comprising administering to the subject a dosage of an agent effective to produce an immune response comprising antibodies against an amyloid component characteristic of said disorder and an adjuvant that augments the immune response to the amyloid component, and thereby effecting prophylaxis of the disorder.

Claim 59. The method of claim 58, wherein said amyloid component is a fibril protein or fibril peptide.

Claim 60. The method of claim 58, wherein the amyloid component is derived from a precursor protein selected from the group consisting of Serum Amyloid A protein (ApoSSA), immunoglobulin light chain, immunoglobulin heavy chain, ApoAl, transthyretin, lysozyme, fibrogen alpha chain, gelsolin, cystatin C, Amyloid beta protein precursor (beta-APP), Beta2 microglobulin, prion precursor protein (PrP), atrial natriuretic factor, keratin, islet amyloid polypeptide, a peptide hormone, and synuclein; including variant proteins associated with hereditary amyloidosis.

Claim 61. The method of claim 60, wherein said agent induces an immune response directed against a neoepitope formed by said amyloid component with respect to said precursor protein.

Claim 62. The method of claim 60, wherein said amyloid component is selected from the group consisting of Ah., AL, ATTR, AapoAl, Alys, Agel, Acys, Abeta, AB2M, AScr, Acal, AIAPP and synuclein-NAC fragment.

Claim 63. The method of claim 62, wherein said agent is selected from the group consisting of AA, AL, ATTR, AapoAl, Agel, Acys, Abeta, AB2M, AScr, Acal, AIAPP and synuclein-NAC fragment.

The Office mailed an Advisory action on 2/12/04 which maintained the objection to some of the claims as follows:

> The objection to claims 13, 15, 16, 60, 62, and 63 as set forth at pp. 4 P10 of the previous Office Action (25 July 2003) is maintained. Until a decision is reached concerning the Applicant's Petition (30 December 2003), said claims contain unelected material. The restriction requirement is still in effect and therefore the objection is maintained.

Applicants filed a request for continued examination on 7/29/04.

DISCUSSION

The application, file history and petition have been considered carefully. In the Petition, Applicants requests reconsideration of the restriction requirement.

Applicants are correct that the restriction requirement failed to identify and properly treat linking claims, which describes the inventions in generic terms and encompass (1) some or all of the inventions in claims 13, 15, 16, 60, 62 and 63 and (2) also include inventions directed at other amyloid components not listed in the claims. The examiner should have included the following paragraph in the Office actions:

> Claims 11 and 58 link(s) inventions of each amyloid precursor proteins of claims 13 and 60. Claims 13 and 60 link(s) inventions of each amyloid component of claims 15, 16, 62 and 63. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additionally, the examiner erred in limiting the examination of the generic linking claims to the elected inventions transthyretin and ATTR. Applicants are correct that they deserve examination of the generic linking claims along with the elected invention.

The objection to claims 13, 15, 16, 60, 62, and 63 as set forth at pp. 4 P10 of the Office Action (25 July 2003) for containing unelected material is also improper in view of the generic linking claims. MPEP 809.04 states that

> Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the case claims to the nonelected invention or inventions.
>
> If a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the nonelected inventions that are linked to the elected invention by such allowed linking claim.

While most of the inventions lack a common structure disclosed as being essential to the common utility, the restriction requirement overlooked the relationship between three pairs of components with regard to shared structure and function. The restriction requirement between ApoSSA and ApoA1 has been withdrawn. The restriction requirement between immunoglobulin light and heavy chain has been withdrawn. The restriction requirement between beta-APP and synuclein has been withdrawn.

In consideration of the traversal, the examiner erred in reasoning that

> the precursor proteins listed in claim 13 and their respective fragments listed in claim 15 are not members of a Markush group.

The components in claims 13 and 15 are listed in the alternative. In that respect, they are members of a Markush group, however the Markush Group contains components which fail to fail to contain a substantial structural feature which is disclosed as being essential to the common utility of treating a disorder characterized by amyloid deposition. For this reason, the components lack "unity of invention" as defined by In re Harnisch and restriction to a single component is proper. See MPEP 803.02, second paragraph. The compounds share no common structure. They result from different genes, contain different mutations, appear in different tissues and in different patient populations.

Applicants are correct that MPEP 803.02 requires concurrent examination of Markush members which are few in number or closely related. However, the many components listed in claims 13, 15, 16, 60, 62, and 63 are not few in number and they are not sufficiently closely related to warrant concurrent examination. Examination of all the components would require serious burden.

DECISION

The petition under 37 CFR 1.144 filed on 04 June 2004 is **GRANTED-in-PART** as follows:

The restriction requirement between ApoSSA and ApoA1 has been withdrawn.
The restriction requirement between immunoglobulin light and heavy chain has been withdrawn.
The restriction requirement between beta-APP and synuclein has been withdrawn.

The restriction requirement to elect a single amyloid component (or pair of components, such as ApoSSA and ApoA1, as set forth above) from the those listed in the Markush groups of claims 13, 15, 16, 60, 62, and 63 is proper because the components fail to have "unity of invention" as defined by In re Harnisch.

Applicants are entitled to an examination of the generic claims 11 and 58 as these claims link the inventions listed in claims 13, 15, 16, 60, 62, and 63.

The objection to the non-elected inventions is withdrawn.

The finality of the Office action mailed 8 April 2004 is withdrawn. The application will be forwarded to the examiner for consideration of the papers filed 7/29/04 and preparation of an Office action which is consistent with this petition decision and which follows linking claim practice with regard to the generic claims.

There is no fee required for the filing of this petition. A credit of $130.00 has been refunded to Applicants' deposit account number 20-1430.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

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